

K132466

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**Wound Management 727 392-1261**

Smith & Nephew, Inc. F 727 392-6914 or 727 392-0797  
970 Lake Carillon Drive Customer Care Center: 1 800 876-1261  
Suite 110 www.smith-nephew.com  
St. Petersburg, FL 33716

**510(k) Summary**

OCT 23 2013

**General Information****Submitters Name/Address:**

Smith & Nephew, Inc.  
970 Lake Carillon Drive  
Suite 110  
St. Petersburg, FL 33716

**Establishment Registration Number:**

3006760724

**Contact Person:**

Laura Reynolds  
Director Regulatory Affairs

**Phone Number:**

(727) 329-7702

**Date Prepared:**

September 20, 2013

**Device Description****Trade Name:**

RENASYS™ EZ MAX Negative Pressure Wound  
Therapy Device

**Generic/Common Name:**

Powered Suction Pump

**Classification Name:**

Powered Suction Pump; 21 CFR 878.4780

Product Code: OMP

**Predicate Device Information**

510(k) #	Device	Clearance Date
K102001	RENASYS EZ PLUS	08/06/2010

**Device Description**

The RENASYS EZ MAX Negative Pressure Wound Therapy NPWT device is a lightweight, suction device intended for wound management via application of continuous or intermittent negative pressure wound therapy to the wound for removal of fluids, including wound exudates, irrigation fluids, and infectious materials. The pump is connected to the wound dressing via a tube connected to a disposable canister. The device provides negative pressure wound therapy to the wound at a range of pressure settings and removes exudates from the wound site to the disposable canister. The device can operate either by a mains power supply or internal battery. The technological characteristics of the new device have not changed. The primary changes made are in relation to compliance with the IEC 60601-1 electrical safety standards. The predicate device complies with the IEC 60601-1 2<sup>nd</sup> edition series while the RENASYS EZ MAX NPWT complies with the IEC 60601-1 3rd Edition series of electrical safety standards

RENASYS EZ MAX NPWT is compatible with existing Smith & Nephew wound dressing kits currently on the market.

### **Indications for Use**

RENASYS EZ MAX is indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials

Examples of appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehiscent wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps and grafts

The RENASYS EZ MAX Professional Healthcare Facility model (66801309) is intended for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

### **Non-Clinical Tests (Bench)**

Testing has been conducted to verify the modifications to the RENASYS EZ MAX device meet design specifications and demonstrate substantial equivalence to the predicate device.

The list below summarizes the bench testing undertaken and successfully completed for the RENASYS EZ MAX NPWT device:

- Pumping capacity is equivalent to the predicate device.
- Device provides negative pressure at individual pressure settings of 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180 and 200mmHg, identical to the predicate device.
- The device delivers negative pressure in a continuous and intermittent operating mode identical to the predicate device.
- The device including canisters interface with existing RENASYS NPWT wound dressing kits.
- Device pressure setting remains unchanged when the device is locked and actuation of the Therapy Knob is attempted
- Device has a protection feature/mechanism to maintain the intended functional state (Continuous ON, OFF, Intermittent ON).
- Device attaches to IV poles ranging in diameter from ½ inch to 2 inches.
- Device bed rail clamp attaches to a bed rail (or equivalent) up to 3 inches in diameter.
- Device canister bracket withstands side impact load simulating a worst case failure mode for clinical use.
- Device complies with the following standards:
  - IEC 60601-1-2:2007(3rd edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, Interpretation Sheet
  - IEC 60601-1:2005 (3rd edition). Medical Electrical Equipment - Part 1:

- General Requirements for Safety,
- ANSI/AAMI ES60601-1:2005 Version (R2012) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-8:2006 (2nd edition) Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical
- IEC 60601-1-6:2010 (3rd Edition) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366:2007 (1st edition) Medical devices - Application of usability engineering to medical devices. (General)

### **Summary of Safety and Effectiveness**

In establishing substantial equivalence to the currently marketed predicate device, Smith & Nephew, Inc. evaluated the indications for use, materials, technology, product specifications and energy requirements of the device. Performance testing and electrical safety testing has been successfully completed to demonstrate that the RENASYS EZ MAX is substantially equivalent to the predicate device and is safe and effective for the intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Smith & Nephew, Incorporated  
Ms. Laura Reynolds  
Director of Regulatory Affairs  
970 Lake Carillon Drive, Suite 110  
Saint Petersburg, Florida 33716

October 23, 2013

Re: K132446

Trade/Device Name: RENASYS™ EZ MAX Negative Pressure Wound Therapy Device  
Regulation Number: 21 CFR 878.4780  
Regulation Name: Powered suction pump  
Regulatory Class: Class II  
Product Code: OMP  
Dated: September 20, 2013  
Received: September 23, 2013

Dear Ms. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K132446

Device Name: RENASYS™ EZ MAX Negative Pressure Wound Therapy Device

### Indications For Use:

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S